



July 27, 2020

Covidien
Jennifer Sullivan
Regulatory Affairs Manager
15 Hampshire Street
Mansfield, Massachusetts 02048

Re: K130904

Trade/Device Name: Trellis-8 Peripheral Infusion System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEY, KRA

Dear Jennifer Sullivan:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated October 25, 2013. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W.
O'Connell -S

Digitally signed by Gregory W.
O'Connell -S
Date: 2020.07.27 08:16:20
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Gregory O'Connell
Assistant Director
Plaque Modification Devices Team
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 25, 2013

Covidien
Ms. Jennifer Sullivan
Regulatory Affairs Manager
15 Hampshire Street
Mansfield, MA 02048

Re: K130904

Trade/Device Name: Trellis-8 Peripheral Infusion System
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous flush catheter
Regulatory Class: Class II
Product Code: KRA
Dated: October 4, 2013
Received: October 7, 2013

Dear Ms. Sullivan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Kenneth J. Cavanaugh -

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for

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Section 4
Indications for Use Statement

510(k) Number (if known):

Device Name: Trellis-8 Peripheral Infusion System

Indications for Use:

The Trellis-8 Peripheral Infusion System is intended for controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kenneth J. Cavanaugh -S



510(K) SUMMARY

1. 510(k) Owner:

Covidien
15 Hampshire Street
Mansfield, MA 02048
Telephone: (508) 452-1659
Fax: (508) 452-1659

Contact: Jennifer Sullivan
Title: Regulatory Affairs Manager
Date Prepared: March 21, 2013

2. Device:

Trade Names: Trellis-8 Peripheral Infusion System
Classification Name: Continuous Flush Catheter
Regulation Number: 21 CFR 870.1210
Product Code(s): KRA
Classification: Class II

3. Predicate Device:

Trellis-8 Peripheral Infusion System K050147

4. Device Description:

The Trellis-8 Peripheral Infusion System enables the physician to isolate a treatment region, infuse a physician-specified fluid, and disperse the fluid by means of oscillation of a Dispersion Wire. The Isolation/Infusion component is a multi-lumen catheter with two compliant balloons at the distal end and infusion holes located between these balloons. The device also has a central lumen that is compatible with a 0.035" guidewire. The Dispersion Wire provides oscillation when activated. The Dispersion Wire is connected to an integral Oscillation Drive Unit (ODU) that oscillates the Dispersion Wire within the isolated region to further disperse the infused fluid. Once the procedure is complete, the contents in the treatment area can be aspirated via the guide wire lumen and the infusion/aspiration (IA) window if desired.

5. Intended Use:

The Trellis-8 Peripheral Infusion System is intended for controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.

6. Technological Characteristics:

The primary differences between the proposed device and the predicate device are the combination of the infusion and aspiration lumens, addition of circumferential infusion technology, and increased catheter amplitude. The modified device has the same fundamental technological characteristics as compared to its predicate device.

7. Performance Data:

Bench top functional testing was completed to support substantial equivalence between the modified device and the current device. The test regimen evaluated the following:

- Mechanical integrity through tensile, kink, catheter trackability, and compliance with sheath and guidewire testing
- Balloon integrity through balloon seal, burst and tensile testing
- ODU and Dispersion Wire integrity through speed, torque and hemostatic valve seal testing

The results of the functional testing show that the modified device continues to meet the product specifications.

Animal testing was conducted to assess vessel trauma between the proposed and predicate devices. The results of animal testing show that the modified device causes no more vessel trauma than the predicate.

Biocompatibility testing per ISO 10993: Biological Evaluation of Medical Devices was completed to support biocompatibility between the modified device and the predicate device. The results of the biocompatibility testing show that the modified devices continue to be biocompatible for its intended use.

The results of functional testing, animal and biocompatibility testing demonstrate substantial equivalence.

8. Conclusion:

Based on bench, animal and biocompatibility testing results, Covidien has demonstrated that the modified Trellis-8 Peripheral Infusion System is substantially equivalent to the existing Trellis-8 Peripheral Infusion System.